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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,859	12/09/2003	Jutta Anna Turck	13101/48202	9112

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EXAMINER	
DUNSTON, JENNIFER ANN	
ART UNIT	**PAPER NUMBER**
1636	

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12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/732,859	TURCK ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,38-42 and 59* is/are pending in the application.

4a) Of the above claim(s) *5 and 6* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,38-42 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/469,211.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/9/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 12/9/2003, in which claims 7-37, 43-58 and 60-61 were canceled. Currently, claims 1-6, 38-42 and 59 are pending.

Election/Restrictions

Applicant's election without traverse of the species CAMV 35S promoter in the reply filed on 9/5/2007 is acknowledged. Claims 1-4, 38-42 and 59 are readable upon the elected species.

Claims 5 and 6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/5/2007.

An examination on the merits of claims 1-4, 38-42 and 59 follows.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of UK 9828660.2 has been filed in parent Application No. 09/469,211, filed on 12/22/1999.

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 12/9/2003, is acknowledged. The signed and initialed PTO 1449 has been mailed with this action.

Specification

The disclosure is objected to because of the following informalities:

1) At page 1, line 1 the status of Application No. 09/469,211 should be updated to indicate that it is now US Patent No. 6,660,524.

2) The paragraph beginning on page 15 at line 29 has been amended to contain the phrase "SSPE= mM 0.280 M" in the amendment filed 4/9/2004. It would be remedial to delete the term "mM."

3) At page 22, line 36 the word "regulator" is misspelled.

Appropriate correction is required.

The use of the trademark PBLUESCRIPT (page 7, lines 28 and 34; page 8, lines 3, 6, 14, 17, 22, 27 and 34; page 20, lines 8, 16 and 25) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: pSK52040 (Figure 5), pSK8040 (Figure 6), and pDV35S1 (Figure 7). The brief description of Figures 5, 6 and 7 does not match the plasmids depicted in each of the figures. The drawings were amended on 11/15/2005 so that Figures 5-7 depict plasmids pSK52040, pSK8040, and pDV35S1,

respectively. While the originally filed specification appears to accurately describe these plasmids, the specification was amended on 4/9/2004 to indicate that Figures 5-7 show plasmids pDV35S1, pSK52040, and pSK58040, respectively. As amended, the specification does not accurately describe the plasmids shown in Figures 5-7. It would be remedial to amend the specification to indicate that Figure 5 is a schematic diagram of the plasmid pSK52040, Figure 6 is a schematic diagram of plasmid pSK58040, and Figure 7 is a schematic diagram of plasmid pDV35S1. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 38 is objected to because of the following informalities: the word "with" in line 2 of the claim should be deleted to improve the grammar of the claim. Appropriate correction is required.

Claim 59 is objected to because of the following informalities: the claim should refer to "claim 38" rather than "claims 38." Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,660,524 (hereinafter the '524 patent).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claim 1 is generic to all that is recited in claim 1 of the '524 patent. That is, claim 1 of the '524 patent falls entirely with the scope of claim 1 of the instant application or, in other words, instant claim 1 is anticipated by claim 1 of the '524 patent. Specifically, claim 1 of the '524 patent is narrower in scope than instant claim 1, because the regulator polypeptide is limited to the amino acid sequence of SEQ ID NO: 2 or an amino acid sequence encoded by a nucleotide sequence that hybridizes to the complement of the nucleotide sequence from 295 to 1035 of SEQ ID NO: 1. This regulator is a species of the genus of

regulators isolated from a prokaryotic source of instant claim 1. Furthermore, instant claims 2-4 are anticipated by conflicting claims 2-4.

Thus, the instant claims, if allowed, would extend patent protection of the '524 invention. Further, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the rights to the '524 invention, then two different assignees would hold patent claims to the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 38-41 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Weinmann et al (The Plant Journal, Vol. 5, No. 4, pages 559-569, 1994, cited as reference C53 on the IDS filed 12/9/2003; see the entire reference).

Regarding claim 1, Weinmann et al teach a nucleic acid molecule comprising a first nucleotide sequence comprising a CAMV 35S 5' regulatory region operably linked to a nucleic acid sequence that encodes a tTa regulatory polypeptide and the octopine synthase transcriptional terminator, and a second nucleotide sequence comprising a 5' regulatory region containing a chimeric promoter consisting of seven tet operator sites linked to a TATA-box, where the regulatory region of the second nucleotide sequence is operably linked to a β-glucuronidase coding sequence (e.g., page 567, Constructs; Figure 2, especially pTetVP16-Top10). Weinmann

et al teach that the expression of the β-glucuronidase coding sequence is controlled by the tTa regulator polypeptide using a tetracycline inducer (e.g., page 565, left column, 1st full paragraph; Figure 4). The tTa regulator taught by Weinmann et al contains the prokaryotic TetR fused to the activation domain of herpes simplex VP16, and the tet operator sequences are isolated from a prokaryotic source (e.g., Abstract; page 559, right column, 2nd full paragraph; paragraph bridging pages 559-560).

Regarding claims 2-4, Weinmann et al teach the constitutive CAMV 35S promoter operably linked to the nucleic acid encoding the tTa regulator polypeptide (e.g., Figure 2).

Regarding claim 38, Weinmann et al teach the step of introducing the pTetVP16-Top10 inducible expression system (described above) into a eukaryotic *Nicotiana tabacum* cell (e.g., paragraph bridging pages 561-562; page 568, Transient expression in tobacco protoplasts; page 568, Tobacco transformation).

Regarding claim 39, Weinmann et al teach the method where the pTetVP16-Top10 expression system is a chemically inducible gene expression system, where the inducer is tetracycline (e.g., page 565, left column, 1st paragraph; Figures 3 and 4).

Regarding claim 40, Weinmann et al teach the method where the β-glucuronidase coding sequence is heterologous to the tobacco cells (e.g., Figure 2).

Regarding claim 41, Weinmann et al teach the method where the expression of the β-glucuronidase coding sequence of the second nucleotide sequence is increased in the absence of tetracycline and is decreased in the presence of tetracycline (e.g., Figures 3 and 4).

Regarding claim 59, Weinmann et al teach tobacco plant tissue transformed by the method of claim 38 (e.g., paragraph bridging pages 561-562; page 568, Transient expression in tobacco protoplasts; page 568, Tobacco transformation; Figures 3 and 4).

Claims 1-3, 38-42 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bujard et al (US Patent No. 5,789,156, cited as reference A03 in the IDS filed 12/9/2003; see the entire reference).

Regarding claim 1, Bujard et al teach a single nucleic acid molecule comprising a first sequence encoding a fusion protein which activates transcription, the fusion protein comprising a first polypeptide which binds to a tet operator sequence in the presence of tetracycline operably linked to a second polypeptide which activates transcription in eukaryotic cells, and a second nucleic acid comprising a nucleotide sequence to be transcribed operatively linked to at least one tet operator sequence (e.g., column 20, line 51 to column 21, line 4). Further, Bujard et al teach that the fusion protein can activates transcription and can bind to a tet operator sequence either (i) in the absence but not the presence of tetracycline, or (ii) in the presence but not the absence of tetracycline (e.g., column 7, lines 21-45). Bujard et al teach that the first sequence encoding the tet-regulated fusion polypeptide additionally contains a promoter and polyadenylation signals (e.g., column 12, lines 15-34). The tet repressor/operator/inducer system taught by Bujard et al is isolated from a prokaryotic source (e.g., column 2, lines 44-61).

Regarding claim 2, Bujard et al teach the nucleic acid molecule where the promoter operatively linked to the nucleic acid sequence encoding the tet-regulator polypeptide is a

promoter that allows expression in eukaryotic cells and tissues (e.g., column 2, lines 44-62; column 12, lines 35-53).

Regarding claim 3, Bujard et al teach the nucleic acid molecule where the promoter operatively linked to the nucleic acid sequence encoding the tet-regulator polypeptide is a constitutive promoter (e.g., column 12, lines 35-53).

Regarding claim 38, Bujard et al teach a method of controlling eukaryotic gene expression, comprising introducing into a eukaryotic cells the above described nucleic acid molecule comprising a tet-inducible gene expression system (e.g., column 2, lines 44-61; column 14, line 61 to column 15, line 61).

Regarding claim 39, Bujard et al teach the method where the inducible gene expression system is a chemically inducible gene expression induced by tetracycline or a tetracycline analog (e.g., column 2, line 44 to column 3, line 13).

Regarding claim 40, Bujard et al tech the method where the second nucleic acid sequence operatively linked to the tet operator encodes a protein that is heterologous in origin with respect to the eukaryote being transformed (e.g., column 36, lines 40-59).

Regarding claim 41, Bujard et al teach the method where the expression of the second nucleic acid sequence is increased from a basal level (e.g., column 3. line 50 to column 4, line 24).

Regarding claim 42, Bujard et al teach the method where an increase in expression of the second nucleic acid sequence is caused by the addition or presence of the tetracycline inducer (e.g., column 3. line 50 to column 4, line 24).

Regarding claim 59, Bujard et al teach plant tissue transformed by the method of claim 38 (e.g., column 14, lines 30-47).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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